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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,506	05/10/2002	Robert Bartlett Elliott	GL216721-003	8690

466 7590 06/02/2005

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EXAMINER

WINSTON, RANDALL O

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/019,506

Applicant(s)

ELLIOTT ET AL.

Examiner

Randall Winston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 28-32 and 37-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-32 and 37-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Acknowledgment is made of receipt and entry of the claims filed on 03/14/2005.

The rejections made under 35 U.S.C. 112, first paragraph and second paragraph have been overcome by Applicant's amendment.

Claims 28-32 and new claims 37-45 are under examination.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28-32 and 37-45 as amended stand rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshikawa et al. (*Enzymatic Release of Pro-Beta-Casomorphin-9 and Beta-Casomorphin-9 from Bovine Beta-Casein*, Department of Food Science and Technology, Kyoto University (1994) pp. 38-42) in view of Wakat (US 6054128) and Kalvinsh et al. (US 5965615) and as evidenced by Spireas (US 6555551)

Applicant claims a composition and/or method comprising an immunomodulating component (i.e. beta-casomorphin-9 or A2 beta-casein) and a fortifying compound to reduce the incidence of a population with cardiovascular disease is apparently claimed.

Yoshikawa et al. teach (see, e.g. entire article) that an immunomodulating component such as beta-casomorphin-9 are inhibitors of the Angiotensin Converting Enzyme (ACE) which is well known in the art to cause hypertension or heart failure. (Please note, as evidenced by

Spirea (see, e.g. column 1 lines 21-24), ACE inhibitors are useful for the treatment of cardiovascular disorders). Therefore, a person of ordinary skill in the art would be motivated to use the ACE inhibitor beta-casomorphin 9 to treat cardiovascular disorders. Yoshikawa et al, however, do not teach that the claimed fortifying compounds can treat cardiovascular diseases.

Wakat beneficially teaches (see, e.g. column 6 lines 41-56) fortifying compounds such as vitamin B6 (Pyridoxine), vitamin B12 (Cobalamin) and folic acid can treat cardiovascular disorders.

Kalvinsh et al. beneficially teach (see, e.g. abstract) a fortifying compound such as betaine can treat cardiovascular disorder such as cardiopathy.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Yoshikawa et al.'s teachings to include the beneficial teachings of Wakat and Calvinsh et al. because the combined teachings of combining the two claimed active ingredients of an immunomodulating component and a fortifying compound would create an improved composition to reduce the incidence of population with cardiovascular disease.

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention made, especially in the absence of evidence to the contrary.

{Please note for claims 29-31, the patentability of a product does not depend upon its method of production. If the product in a product-by-process claim is the same or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process." (see, e.g. MPEP 2113)}

**No claims are allowed.**

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status

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information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Susan D. Coe*  
5-27-05

**SUSAN COE  
PRIMARY EXAMINER**